

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., NORTON
(WATERFORD) LTD., and TEVA
PHARMACEUTICALS USA, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC, AMNEAL IRELAND
LIMITED, AMNEAL
PHARMACEUTICALS LLC, AND
AMNEAL PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 23-cv-20964-SRC-
MAH

ELECTRONICALLY STORED INFORMATION PROTOCOL (“ESI”) PROTOCOL

WHEREAS, the above-captioned action, brought by Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, “Plaintiffs”) against Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc, (collectively, “Defendants”) (together, the “Parties,” and each individually a “Party”) is pending before this Court;

WHEREAS, the Parties have engaged in discussions regarding the format of production of documents and electronically stored information (“ESI”) that are responsive to requests made by the Parties;

WHEREAS, Counsel for the Parties agree to meet and confer regarding search terms and custodians to be searched in good faith to promote the resolution of disputes regarding discovery of ESI without Court intervention. The Parties, by and through their attorneys, stipulate and agree

to this ESI Protocol (the “Protocol”) governing the production of documents, including ESI, in the above-captioned action (the “Action”) as follows:

I. DEFINITIONS

A. “**Documents**” shall have the same meaning as in Federal Rule of Civil Procedure 34.

B. “**Electronically stored information**” or “**ESI**”, shall have the same meaning as in Federal Rule of Civil Procedure 34. Unless otherwise specified, the terms Document and ESI are used interchangeably throughout this Protocol.

C. “**Extracted Text**” means the text extracted from a Document, and includes all header, footer, and Document body information when available.

D. “**Load/Unitization file**” means an electronic file containing information identifying a set of paper-scanned images or processed ESI and indicating where individual pages or files belong together as Documents, including attachments, and where each Document begins and ends. A Load/Unitization file will also contain data relevant to the individual Documents, including extracted and user created Metadata, as well as OCR or Extracted Text, should such data be available.

E. “**Media**” means an object or device, including but not limited to a disc, tape, computer or other device, on which data is or was stored.

F. “**Metadata**” means (i) information associated with a native file that is not ordinarily viewable or printable from the application that generated, edited, or modified such native file which describes the characteristics, origins, usage or validity of the electronic file or (ii) information generated automatically by the operation of a computer or other information technology system when a native file is created, modified, transmitted, deleted or otherwise manipulated by a user of such system.

G. “**Native data format**” means and refers to the format of ESI in which such ESI was generated or used by the producing party in the usual course of business and in its regularly conducted activities.

H. “**OCR File**” means the optical character recognition file which is created by software used in conjunction with a scanner that is capable of reading text-based Documents and making such Documents searchable using appropriate software.

I. “**Parties**” means or refers to the named plaintiffs and defendants in the above captioned matter, as well as any later added plaintiffs and defendants.

J. “**Non-party**” means any entity not included in the caption to this matter.

K. “**Protected Data**” means any information that a party believes to be subject to federal, state, or foreign data protection laws or other personally identifiable information or sensitive healthcare information.

L. “**Static Image**” means or refers to a representation of ESI produced by converting a native file into a standard image format capable of being viewed and printed on standard computer systems. A Tagged Image File Format (TIFF) image is an example of a Static Image.

II. PRODUCTION FORMAT

A. **ESI**. Documents gathered from electronic data shall be produced in the following format:

1. **TIFFs or JPEGs**. For black and white documents, single-page TIFF (Tagged Image File Format) images with CCITT group 4 compression, 300 DPI resolution, and for color documents where color is necessary to understand the meaning of the content of the document, JPEG (Joint Photographic Experts Group) format images with compression and a high-quality setting as to not degrade the original image. For avoidance of doubt, presentation files shall be produced in JPEG format.

2. Unique IDs. Each image should have a unique file name, using the Bates Number of the first page of the document. Bates Numbers shall be unique IDs with a prefix that can be readily attributed to the producing Party. Bates Numbering should be sequential. If a Bates Number or set of Bates Numbers is skipped in a production, the producing Party will so note.

3. Documents in Native Format. If good cause exists to request production of certain files in native format, the Requesting Party may request such production and provide an explanation of the need for native file review of the particular files for which such review is considered necessary. When producing files in native format, the producing Party will also provide a single-page placeholder TIFF file referencing the native file with a Bates Number and Confidentiality designation for the file.

4. Load Files/Cross-Reference Files. Documents produced shall be provided with (i) Concordance delimited load file(s), and (ii) Opticon delimited cross-reference file(s). Every TIFF/JPEG in each production must be referenced in the production's corresponding load file. The total number of images referenced in a production's load file should match the total number of TIFF/JPEG files in the production. The database load file shall include a reference to any native files that are produced.

5. Parent-Child Relationships. Parent-child relationships (the association between an e-mail and files physically attached) should be preserved. Email attachments should be produced sequentially after the parent email.

6. Text Files. For each document, a document level text file should be provided along with the TIFFs/JPEG/native files at the time of production of the corresponding TIFFs/JPEG/native files. If the document contains extractable text, the extractable text should be provided. If the document does not contain extractable text, the producing Party may provide OCR

for that document. Documents with redactions shall be produced with OCR text files. Text files for documents with redactions will not contain the redacted portions of the documents.

7. Metadata Fields. The following metadata should be provided if it exists: (i) all metadata as set forth in Exhibit A; (ii) metadata pertaining to time/date standardized across the collection to a particular time zone, such as UTC. The time zone used during processing will be included in a metadata field called TimeZone. The Parties reserve their rights to object to any request for the creation of metadata for documents that do not contain metadata in the original. For the avoidance of doubt, no Party has an obligation to create or manually code metadata fields that do not exist as part of the original metadata of the electronic document except for: (a) BegBates; (b) EndBates; (c) BegAttach; (d) EndAttach; (e) AttachRange; (f) PageCount; (g) Confidentiality; (h) Redaction; (i) Custodian and (j) All Custodians. Custodians should be identified using the convention "Last Name, First Name." The Parties may rely on the metadata automatically generated by the processing of the ESI, and no Party has an independent obligation to review the metadata of individual files to ensure the metadata's accuracy.

8. De-duplication. The producing Party shall de-duplicate ESI that is exact and identical across all custodians' ESI. The Parties may use and rely in good faith on reasonable electronic means of de-duplicating documents or files.

9. Email Thread Suppression. The producing Party may also de-duplicate emails in such a way as to eliminate earlier or incomplete chains of emails, and produce only the most complete iteration of an email chain.

10. Track Changes. Documents containing track changes will be processed with track changes exposed. To the extent reasonably practicable, produced TIFF and JPEG images will show all text and images that are visible, with the exception of redacted portions.

Hidden content, track changes or edits, comments, notes and other similar information, to the extent available with a document in its native file format, shall to the extent reasonably practicable, also be imaged so that such content is viewable in the image file.

11. Hidden Content. Excel files and other spreadsheets will be processed so that the extracted text file contains all columns and rows and any hidden information. PowerPoint and other presentation files shall be produced with speaker notes exposed.

12. Foreign Language Documents. All documents shall be produced in their original language. Where a requested document exists in a foreign language and the producing Party also has an English-language version of that document that it prepared for non-litigation purposes prior to filing of this Action, the producing Party shall produce both the original document and all English-language versions. In addition, if the producing Party has a certified translation of a foreign-language document that is being produced (whether or not the translation is prepared for purposes of litigation), the producing Party shall produce both the original document and the certified translation. Nothing herein shall require a producing Party to prepare a translation, certified or otherwise, for foreign language documents that are produced in discovery.

13. Databases. The Parties agree to meet and confer on the identity of any databases and/or files created in proprietary applications (e.g., structured data), and the format in which responsive data should be produced from those systems to the extent reasonably possible (e.g., export to Microsoft Access or SQL).

III. PRODUCTION MEDIA AND ENCRYPTION OF PRODUCTIONS

Unless otherwise agreed, the Parties shall provide document productions in the following manner: the producing Party shall provide the production data on external hard drives or by FTP transfer, as appropriate. The producing Party shall forward the password to decrypt/unlock the

production data separately from the external drive on which the production data is saved, or email containing the FTP transfer link.

IV. EXCLUDED CATEGORIES OF ESI

Absent a showing of good cause by the requesting Party, the following categories of ESI need not be preserved or produced: (i) deleted, fragmented, or other data only accessible by forensics; (ii) random access memory (RAM), temporary files, or other ephemeral data that are difficult to preserve without disabling the operating system; (iii) on-line access data such as temporary internet files, history, cache, cookies, and the like; (iv) back-up data that are substantially duplicative of data that are more accessible elsewhere; (v) voice messages; (vi) electronic mail or pin-to-pin messages sent to or from mobile devices (e.g., iPhone, Android, and Blackberry devices), provided that a copy of such mail is routinely saved elsewhere; (vii) other electronic data stored on a mobile device, such as calendar or contact data or notes, provided that a copy of such information is routinely saved elsewhere; (viii) logs of calls made from mobile devices; (ix) messages from messaging forums (e.g. Slacks or Microsoft Teams); (x) server, system or network logs; (xi) electronic data temporarily stored by laboratory equipment or attached electronic equipment, provided that such data is not ordinarily preserved as part of a laboratory report; (xii) data remaining from systems no longer in use that is unintelligible on the systems in use; and (xiii) files identified as zero bytes in size and any logo files such as logos incorporated into email signatures.

V. TECHNOLOGY ASSISTED REVIEW

A. Technology Assisted Review (“TAR”), as defined herein, shall mean and refer to a process of machine learning to assist in the categorization and ranking for review of a collection of documents using a computerized system that utilizes the decisions that a Party, or its counsel,

has made on a smaller subset of the collection and then applies those decisions to the balance of the document review population. The use of search terms will not preclude the Parties' use of other reasonable review tools, including TAR. The Parties agree that a producing Party is best situated to evaluate the procedures, methodologies, and technologies appropriate for producing their own hard-copy and ESI. If a producing Party intends to use TAR to cull documents for review and production, the producing Party shall disclose the TAR software that will be used, as well as whether a TAR 1.0 or TAR 2.0 (CAL) workflow will be implemented. When the producing Party determines that further review of documents in the TAR population is disproportionate, the producing Party will disclose the validation processes used to support ceasing review.

B. Nothing in this ESI Protocol prevents a Party from reviewing and analyzing information identified by search terms and/or TAR to determine whether that information is responsive to a request for production and withholding documents determined to be non-responsive. Further, the mere fact that a document hit on or is captured by the application of any agreed upon search terms does not mean that such document is necessarily responsive to any propounded discovery request or is otherwise relevant to this litigation.

VI. REDACTIONS AND MATERIAL EXEMPTED FROM DISCLOSURE

A. The Producing Party may redact from any TIFF/JPEG image, metadata field, or native file material that is protected from disclosure by applicable privilege or immunity or that is required by applicable law or regulation. Redactions must be limited to only language or information within documents deemed protected. The Producing Party shall identify redactions clearly on the face of any TIFF image, either with "Redacted-Privileged" or the redaction reason on the face of the document.

B. Fully non-responsive attachments that are part of responsive families need not be produced. If a Party withholds a fully non-responsive attachment, that producing Party will produce a Bates numbered slip sheet in place of the attachment. The Bates numbered TIFF slip sheet for each withheld attachment shall contain the following language: “Non-Responsive Attachment.” The receiving Party retains the right to request the production of any attachment withheld solely on the grounds of non-responsiveness. The Parties agree to meet and confer in good faith regarding any disputes arising under this section. If the issue cannot be resolved or dropped, the Parties will seek resolution from the Court.

C. Non-responsive parent emails that are part of responsive families must be produced. However, parent emails may be redacted to the extent it contains non-responsive Confidential or Highly Confidential Information, as that term is defined in the Stipulated Discovery Confidentiality Order entered in this case on March 7, 2024 [Provide Citation]. The Producing Party may redact the non-responsive portion(s) of the document containing the Confidential or Highly Confidential Information provided that the redactions do not obscure the meaning of the responsive portions of the document. All such redactions shall be clearly marked on the face of the documents. The receiving Party retains the right to request the production of information redacted solely on the grounds of non-responsiveness. The Parties agree to meet and confer in good faith regarding any disputes arising under this section. If the issue cannot be resolved or dropped, the Parties will seek resolution from the Court.

D. To the extent a responsive document contains non-responsive Confidential or Highly Confidential Information, as that term is defined in the Stipulated Discovery Confidentiality Order in this case, the Producing Party may redact the non-responsive portion(s) of the document containing the Confidential or Highly Confidential Information provided that the

redactions do not obscure the meaning of the responsive portions of the document. All such redactions shall be clearly marked on the face of the documents and shall bear a designation indicating that non-responsive Confidential or Highly Confidential Information has been redacted. The receiving Party retains the right to request the production of information redacted solely on the grounds of non-responsiveness. The Parties agree to meet and confer in good faith regarding any disputes arising under this section. If the issue cannot be resolved or dropped, the Parties will seek resolution from the Court.

VII. PRIVILEGE LOGS

Documents withheld from a production pursuant to an attorney-client, work product, or other applicable privilege or immunity, shall be identified on a hybrid categorical privilege log, which shall be provided by the producing Party in a format that can be easily searched and sorted (*e.g.*, Excel). For each document withheld, the producing Party may provide a “Hybrid Categorical Privilege Log” with the following information:

- a. Extracted metadata (Custodian, All Custodians, Email Subject, Title, Date/Time Sent, To, From, CC, BCC, Author, File Name, Date/Time Last Mod, Date/Time Created, and Document Extension) to the extent it is applicable and/or reasonably available for the ESI being withheld and does not reflect the privileged and protected information;
- b. Attorneys in the To, From, CC and BCC metadata fields shall be identified by using symbols, such as an asterisk, within the log itself;
- c. A listing of the privilege source for each entry if not apparent in the To, From, CC and BCC fields;
- d. A listing of any and all applicable categories from the predetermined and agreed upon privilege category descriptions; and
- e. The type and nature of the privilege asserted (*e.g.*, attorney-client privilege, work product doctrine, etc.)

The Parties agree that certain privileged communications or documents need not be included in a privilege log: (a) communications between either Party (or their employees, agents,

and representatives) and that Party's counsel relating to this Action and created on or after the day that Amneal sent its Notice Letter, (b) any work product relating to this Action created after the initial complaint in this Action was filed, (c) any internal communications within a law firm relating to this Action (or among different law firms representing the same clients in this Action), and (d) any communications regarding litigation holds or preservation, collection, or review in direct connection with this Action.

VIII. INCORPORATION OF STIPULATED DISCOVERY CONFIDENTIALITY ORDER

The Confidentiality Order entered by the Court is expressly incorporated herein by reference including, but not limited to, Federal Rule of Evidence 502(d), governing the disclosure of privileged or work product material.

IX. SEARCH TERMS

Not later than June 7, 2024, plaintiffs and defendants will exchange a proposed set of search terms to be used to collect documents from their own respective ESI repositories, and a list of the repositories proposed to be searched. The parties will negotiate in good faith and meet and confer as to those search terms by June 11, 2024. That negotiation may include proposing additional or different reasonably and narrowly-tailored search terms. The parties agree to continue to negotiate in good faith, and need to reach agreement or impasse on those search terms and repositories by June 18, 2024. If the parties cannot reach agreement on search terms and/or repositories by June 18, 2024, they will submit a joint letter to the Court by no later than June 21, 2024 presenting their disagreement(s) for resolution by the Court.

IT IS SO STIPULATED AND AGREED this 31st day of May 2024 by:

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*(Waterford) Ltd., and Teva Pharmaceuticals
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SO ORDERED.

SO ORDERED

Hon. Michael A. Hammer, U.S.M.J.

s/Michael A. Hammer

Michael A. Hammer, U.S.M.J.

Date: 6/3/24

Exhibit A

FIELD NAME	DESCRIPTION
BegBates	Bates number of the first page of a document
EndBates	Bates number for the last page of a document
BegAttach	The BeginBates value of the parent document in a document family
EndAttach	The EndBates value of the last attachment in a document family
AttachRange	The Bates range of documents included in an attachment group (parent document and attached documents) or message unit (email and attachments). AttachRange value will be identical for all members of an attachment group or message unit
Custodian	Custodian of the file or archive from which the file was obtained
All Custodians	All custodian names that possessed a file identified during deduplication
File Name	File system name of an electronic file or email as it appeared on disk in its original location
Title	Title of the document
From	Sender for an e-mail.
To	Members of the To list in the email.
cc	Members of the CC list in an email.
Bcc	Members of the BCC list in an email
Email Subject	The Subject line of an email
Date/Time Sent	Date and time email was sent (mm/dd/yyyy hh:mm:ss)
Date/Time Received	Date and time email was received (mm/dd/yyyy hh:mm:ss)
Date/Time Created	File system Date and time Created value (mm/dd/yyyy hh:mm:ss)
Date/Time Last Modified	File system Date and time Last Modified value (mm/dd/yyyy hh:mm:ss)
Sort Date/Time	Date and time taken from (Email) Date/Time_Sent, (Email) Date/Time_Rcvd, or (EDocs) Date/Time_Modified, repeated for parent document and all children items to allow for date sorting.
Author	Value of the Author field from the Properties of the original file
Document Type	The type of document (hardcopy) or electronic file (e.g., Word, PDF, etc.) typically indicated by the file's extension
Document Extension	File Extension Original or the original file
File Size	Size of the file
PageCount	Number of pages in a file
File Path	The path from a drive root to the folder in which a document was stored or the path from the root mailbox folder to the email folder in which it was stored

MD5 Hash	Unique digital signature of a file; obtained using the MD5 hashing algorithm
ThreadID	Email Thread Identification
TimeZone	Time Zone used for processing data
InternetMessageID	Globally unique identifier for a message which typically includes message ID and a domain name
InternetReplyID	Internet message ID of the Email replied to
Confidentiality	Confidentiality designation of a document
Redaction	Indicates if a document has been redacted ("Y")
Native Link	Contains path to the native files in the production
Text Link	Contains path to the .txt files in the production